IN THE DRAWINGS:

Please amend FIG. 5 of the drawings as shown in the attached replacement drawing figure. FIG. 5 has been amended to include a longitudinal axis through the support needle. No new matter has been added.

Remarks

The Office Action of April 30, 2010, has been received and reviewed. All claims currently under consideration stand rejected. The application is to be amended as previously set forth. All amendments are made without prejudice or disclaimer. Reconsideration is respectfully requested.

Per the suggestion of the Examiner, the "flexible needle catheter" has been more precisely defined in the independent claims to identify that it is made of a material that has a sufficiently high tensile strength to maintain structural integrity during insertion into and retraction from a subject's body, but also possesses sufficient transverse flexibility to deform and accommodate patient motion to reduce irritation therefrom after insertion. Basis for these amendments can be found, inter alia, in paragraph **[0036]**. The amendments to the claims clarifying that that the "kink sleeve" finds basis in, inter alia, paragraphs **[0013], [0019]**, **[0049]**, **[0050]**, and FIG. 3 of the as-filed patent application. No new matter has been added.

Personal Interview

The applicants would like to thank the Office for the courtesy extended the applicants' representatives at the personal interview with the Examiner on June 8, 2010 at 11:00 a.m. Attending the interview on behalf of applicants were Mr. N. Sandor Racz and Allen C. Turner.

At the interview, the outstanding Office action was discussed as were the arguments presented herein. Specifically discussed were flexible kink sleeves, and a "white paper" that references use of the device, and proposed claim language that would not be acceptable. The specification and drawing questions, written description, anticipation, and obviousness rejections were discussed. Exhibits of devices utilizing the invention and the McWha patent were presented. Although no agreement was reached, the applicants believe the interview proved productive in discussing the parties' points of view and possibility for patentable subject matter.

Applicants believe that the foregoing, taken with this Amendment adequately sets forth the substance of the interview. If, however, the Office has further questions or believes that further detail would be beneficial, the Examiner is kindly requested to contact the applicants' undersigned attorney, and further detail will be promptly provided to the extent available.

SPECIFICATION AND CLAIM OBJECTIONS:

The specification has been objected to as failing to provide proper antecedent basis for the claim element that the leading edge of the flexible needle is oriented perpendicular to a longitudinal axis of the support needle. Responsive to the Examiner's objection, applicants have amended the specification at paragraph **[0037]** to specifically articulate this particular aspect of the leading edge of the flexible needle. Applicants respectfully submit that this amendment is supported by the disclosure in FIG. 5 as originally filed which clearly shows the leading edge of tip 29 of the flexible needle being positioned perpendicular to the longitudinal length of the support needle 19. Although applicants submit that the location of the longitudinal axis of the support needle would be readily apparent to a person of ordinary skill in the art, for further clarity applicants have amended FIG. 5 to specifically identify the longitudinal axis of the support needle. In view of these amendments, applicants respectfully submit that the specification adequately discloses the leading edge to support the limitation in the claims.

Applicants have also addressed the objection of the Examiner to Claim 1 by deleting the space which separates the wording of the claim and the period at the end of the claim.

In view of these considerations, applicants respectfully request a withdrawal of the objections to the specification.

35 U.S.C. §112

Claim 34 stands rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Applicants respectfully traverse the rejection. Claim 34 requires that the leading edge of the flexible needle be oriented perpendicularly to the longitudinal axis of the support needle. The Examiner maintains that the specification lacks any mention of the angle between the leading edge of the flexible needle catheter and the longitudinal axis of the support needle. Applicants respectfully submit that the spatial relationship of the leading edge of the flexible needle and the longitudinal axis of the support needle is clearly shown in FIG. 5 of applicants' drawings. As shown in FIG. 5 the leading edge of tip 29 of the flexible needle (identified by reference number 29A in the attached Exhibit A) is oriented

perpendicularly to the longitudinal axis of the support needle (identified by the referenced number 19A on the attached Exhibit A). As noted above, applicants have amended the specification to textually identify the spatial relationship of the leading edge of the flexible needle relative to the longitudinal axis of the support needle. In view of these amendments, applicants respectfully submit that claim 34 presently meets the requirements of 35 U.S.C. §112 and therefore the instant rejection should be withdrawn.

35 U.S.C. §102:

Claims 1-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27, 27, 29 and 32-34 stand rejected under 35 U.S.C. §102(b) over McWha. Applicants have amended the referenced claims of the application in order to avoid the instant rejection.

As amended, all of the referenced claims require that the leading edge of the flexible needle be positioned contiguous to the opening in the support needle which communicates with the interior lumen of the support needle. This particular feature of the instant invention is important due to the nature of the operation of the invention.

As detailed in applicants' specification, the invention is adapted for supplying a quantity of medicament to the intrathecal space of a patient. The structure of the invention provides a means of introducing the proximal end of the catheter 15 into that space so that a quantity of medicament may be transported through a hollow lumen or bore defined within the catheter and thereafter outwardly through the proximal end of the catheter into the intrathecal space. Since the user is unable to visually verify the location of the proximal end of the catheter once it is introduced into the patient's body, the invention provides a means to notify the user when the proximal end has entered into the intrathecal space. This notification means can take various forms, for example, the support needle which is housed within the catheter defines an interior lumen which communicates with a visual inspection window on a distal end of the lumen. The proximal end of the interior lumen communicates with an opening defined within the sidewall of the support needle. Once the support needle penetrates into the intrathecal space the cerebrospinal fluid (CSF) within the intrathecal space enters the opening in the support needle and flows through the lumen to the visual inspection window which is positioned outside of the

patient's body. The user may then observe the flow of CSF through the visual observation window and thereby confirm that the opening in the support needle is positioned within the intrathecal space. Since the leading edge of the catheter is positioned contiguous with the opening, the user can also have confidence that the leading edge, i.e., the proximal end of the catheter, is likewise within the intrathecal space. Once the user has confirmed that the proximal end of the catheter is positioned within the intrathecal space, the user may then withdraw the stylet positioned within the lumen of the support needle and the support needle itself from within the interior lumen of the catheter. Removal of these two elements opens up the lumen within the catheter for purposes of the user directing a flow of medicament through that lumen into the intrathecal space. It follows that an important element of the instant invention is the provision of a notification means whereby the user can verify the positioning of the proximal end of the catheter within the intrathecal space. In the claimed aspect of the invention, this notification means includes positioning the pencil tip and the opening of the support needle outside of the lumen of the flexible needle. Furthermore the leading edge of the flexible needle is positioned contiguous to the opening of the support needle. This particular orientation of these constituent elements of the invention provides a structure which provides the desired notification function.

Of considerable importance to Applicants' invention is the ability of the catheter to accommodate the physical movements of the patient after the insertion of the catheter into the patient's body. As set forth in Claim 1, the flexible needle is fabricated from plastic to have a sufficiently high tensile strength and integrity to permit the insertion and retraction of the flexible needle into the patient while also possessing sufficient transverse flexibility that the flexible needle can deform while it is inserted into the patient in order to accommodate movements of the patient thereby reducing irritation to the patient.

Applicants respectfully submit that the McWha reference neither anticipates nor suggests the particular structural elements of the instant invention which constitute this means of verifying or notifying the position of the proximal end of the catheter.

The McWha device utilizes a completely different methodology from that adopted by the applicants' invention. In McWha, medicament is provided to the subarachnoid space by the spinal needle 22. The spinal needle 22 is disposed within the lumen of an epidural needle 12

having a beveled leading edge 16. The needle 22 defines an internal lumen which communicates with an exit port or opening 29 defined on the proximal end of the needle 22. During the insertion process, the proximal end of the needle 22 is retained within the lumen of the epidural needle 12 as illustrated in FIG. 2. In this configuration, the leading edge 16 of the epidural needle forms a cutting head or point for purposes of penetrating the patient's skin and epidermal layers. Once the leading edge has passed through the epidural layers 41 and 42 and penetrated into the epidural space 44 (FIG. 6) the penetration of the epidural needle 12 of the needle assembly is arrested. The user then inserts the spinal needle 22 through the dura mater 46 by threadingly displacing the spinal needle 22 through the lumen of the epidural needle 12. This displacement is accomplished by use of the male threads 33 and the female threads 32. It follows that in the McWha device, the internal needle 22 alone is adapted to penetrate into the subarachnoid space while the outer needle 12 does not penetrate that space. As illustrated in FIG. 6, the outer needle 12 remains outside of the subarachnoid space during the entire operation.

More specifically, FIG. 2 of the McWha discloses the configuration of the McWha device during its use in penetrating the patient's epidermal layer. As shown, the tip 26 of the spinal needle 22 is shown retained within the lumen defined within the epidural needle 12, contrary to the requirements of applicants' claim that the tip 26 and the opening 29 are positioned outside of the lumen of the exterior needle, i.e., the counterpart epidural needle 12. As shown in FIG.s 3 and 6, and further more as set out in col. 5, lines 7-60, McWha does not teach the positioning of the opening 29 in a contiguous spatial relationship with the leading edge 16 of the epidural needle 12 during the final insertion operation. Instead of adopting applicant's approach of positioning the leading edge of the outer needle contiguous with the opening in the support needle, McWha determines the final placement of the opening 29 within the subarachnoid space by the noting the number of threads 32 and 33 or alternatively by the use of markings or other indications on the hub of the assembly which serve to identify the positioning of the end of the spinal needle 22 relative to the proximal end of the epidural needle 12.

Neither the text of McWha's specification nor the drawings of that disclosure appears to disclose the positioning of the pencil point tip and the opening of the spinal needle 22 outside of the bore of the epidural needle 12 and the simultaneously spatial positioning of the leading edge

16 of the epidural needle in a contiguous relationship with the opening.

Applicants respectfully submit that the McWha device neither teaches nor suggests positioning an opening in a support needle in a contiguous spatial relationship with the leading edge of a flexible needle in a needle assembly wherein the support needle is disposed within an internal lumen of a flexible needle as presently claimed by the applicants. As noted above, the operation of the McWha device is markedly different from that utilized by applicants. The McWha device does not require the entry of the flexible needle into the target region wherein medicament is to be introduced. It follows that McWha does not need to address the question of verifying the location of the proximal end of the needle 12) within the subarachnoid space. Instead, in the McWha device since only the spinal needle 22 is required to enter the target region, McWha is only concerned with verifying the location of the opening 29 of the spinal needle 22. Furthermore, since the joint displacement of the needle 12 and needle stops once the two needles have reached the epidural space 44, and the needle 22 proceeds thereafter independent of the needle 12, the spatial relationship of the leading edge 14 of the needle 12 and the opening 29 is of no further relevance under the McWha approach.

In the instant claimed device, the contiguous placement of the opening of the support needle and the leading edge of the catheter is required in order for the user to verify the positioning of the proximal end of the catheter within the patient's body and more specifically the positioning of the proximal end of the catheter within the intrathecal space of a patient. The McWha does not require such an orientation since the positioning of the proximal end of the epidural needle 12 within the subarachnoid space is neither contemplated nor desired in the disclosed operation of the McWha device.

Since the functional approaches of the two devices are markedly different from one another, the structures adopted for use in the two approaches are dissimilar. McWha has no need to position the opening 29 of the spinal needle 22 outside of the lumen of the needle 12 and contiguous to the leading edge 16 of the epidural needle 12 Such a positioning achieves no purpose for the operation of the McWha device. In contrast, in the claimed device such a positioning of these component elements provides a valuable verification function.

In summary, Applicants' claims specify that the pencil point tip and the opening of the

support needle are positioned outside of the bore or lumen of the flexible needle. As amended the claims further require that the opening is positioned contiguously with the leading edge of the catheter. As noted above, this particular orientation of these three elements is important for the operation of the applicants' device. McWha neither discloses nor suggests this particular orientation.

Claim 1 is directed to a device wherein the outer flexible needle is adapted for conveying a medicament to the intrathecal space. As noted in applicants' specification, the disposition of the lumen which actually conveys the medicament within the outermost needle of the assembly assures that the diameter of this medicament conveying lumen can be dimensioned to be the largest possible for a given needle assembly. See paragraph [0011] of applicants' specification. The McWha device does not provide this particular advantage of applicants' claimed device. The McWha device positions the medicament carrying lumen in an interior needle, i.e., in spinal needle 22. As verified by the disclosure of FIG. 6, the dimensionally larger lumen of the epidural needle 12 is not adapted to penetrate the subarachnoid space.48 and therefore it cannot be utilized to convey a medicament into the subarachnoid space. It follows that the McWha reference is not directed to a structure which provides a medicament conveying lumen having the largest diameter for a given needle assembly.

Claim 1, as amended, further provides for a flexible needle catheter which is fabricated from plastic and has a sufficiently high tensile strength to maintain structural integrity during and after insertion into a patient's body as well as retraction therefrom. This flexible needle is also adapted to possess sufficient transverse flexibility to deform and accommodate patient motion after insertion to thereby reduce patient irritation. Applicants respectfully submit that the McWha reference neither recognizes the need for this structural limitation nor does McWha make provision for such a structure.

Claims 14 and 25 have been further amended to require that the kink sleeve be flexible. As noted above, applicants' claimed structure is adapted to facilitate not only an insertion of the flexible needle but also the flexibility of the needle during its residency within the patient's body so as to minimize irritation to the patient. By requiring that the kink sleeve be flexible, applicants' assembly provides further structure to address this objective of providing flexibility

and reducing the likelihood of irritation. Applicants respectfully submit that McWha neither recognizes the need for flexibility in a kink sleeve nor does it appear that McWha provides such a flexible kink sleeve in his construction.

Claims 3 and 20 include the further element that the leading edge of the flexible needle is configured and arranged to provide a feedback signal to indicate dural puncture. Applicants respectfully submit that this feature is neither taught nor disclosed in the McWha reference. As shown in FIG. 6 and as further indicated in col. 5, lines 7-60 of the McWha text, the leading edge of the epidural needle 12, which *arguendo* corresponds to the flexible needle of applicants' claims, does not penetrate the dura mater layer 46. In fact, as shown in FIG. 6, the furthermost point of the leading edge 16 of the epidural needle 12 is spacedly removed from any contact with the dura mater 46. There does not appear to be any disclosure in the McWha reference which teaches or suggests that the epidural needle 12 is fitted with any means of providing a feedback signal to indicate dural puncture. To fit the epidural needle with such structure would make no sense given the operation of the McWha device. In view of this consideration, applicants submit that claims 3 and 20 distinguish over the McWha reference and the rejection of those claims should be withdrawn.

Claim 34 includes the element that the leading edge of the flexible needle is oriented perpendicular to the longitudinal axis of the support needle. This configuration of the leading edge is possible because the instant claimed structure relies on the pencil pointed tip 27 of the support needle to perform a penetration function in the insertion of the needle assembly into the patient's epidermis as opposed to the leading edge of the flexible needle. Applicants respectfully submit that the McWha reference neither teaches nor suggests this particular element.

In FIG.s 4 and 4a, McWha teaches a leading edge 16 which is oriented at approximately 45 degrees to the longitudinal axis of the spinal needle 22 See also col. 4, lines 57-67, wherein the angle θ, as illustrated in FIG. 4, is defined as being 45 degrees in degree measure. Clearly, the drawings and the text of the McWha reference do not teach a construction having a leading edge positioned perpendicularly to the longitudinal axis of the support needle. Given the operation of the McWha reference and the reliance on the leading edge 16 of the epidural needle as a means of penetrating the patient's skin, it stands to reason that the leading edge would need

to be inclined at an angle to the longitudinal axis of the spinal needle 22 in order to form a point for purposes of penetrating the patient's epidermis. Orienting the leading edge 16 perpendicular to the longitudinal axis of the spinal needle 22 would present a leading edge which would not provide a configuration suited for penetrating the patient's epidermis. In view of these considerations, the applicants respectfully that the McWha reference neither teaches nor suggests a flexible needle having a leading edge which is oriented perpendicular to the longitudinal axis of a support needle. Applicants therefore submit that the rejection of claim 34 should be withdrawn.

In view of the above considerations, applicants respectfully submit that the rejection of Claims 1-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27, 27, 29 and 32-34 under 35 U.S.C. §102(b) over McWha should be withdrawn

35 U.S.C. §103:

Claim 28 is rejected under 35 U.S.C. §103 over McWha. Applicants respectfully traverse the rejection. Claim 28, by virtue of its dependency from claim 27, now includes the element of a support needle which defines a pencil point tip and an opening wherein the opening is positioned contiguous to the leading edge of a flexible needle. As noted above, the McWha reference neither teaches nor suggests such an element. In view of the absence of a teaching of this element in the McWha reference applicants respectfully submit that the rejection under 35 U.S.C. §103 should be withdrawn.

Claims 30 and 31 are rejected under 35 U.S.C. §103 over McWha in view of Gribbons. Applicants respectfully traverse the rejection. Gribbons has been cited ostensibly for its teaching of a flat ribbon internal spring. Claims 30 and 31 depend from Claim 1 and therefore now include the element of a support needle having an opening which is positioned contiguous to the leading edge of a flexible needle in which the support needle is housed. As established above, the McWha reference neither teaches nor suggests such an element. Furthermore, the Gribbons reference likewise does not appear to teach or suggest such an element. It follows that any combination of these two references could not teach nor suggest such an element. In view of this

consideration, applicants respectfully submit that the rejection of claims 30 and 31 should be withdrawn.

In view of the foregoing amendments and remarks, applicant respectfully requests reconsideration of the claims of his application.

Respectfully submitted,

Laurence B. Bond
Registration No. 30,549
Attorney for Applicants
TRASKBRITT, P.C.
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: 30 October 2010
Enc: Replacement Drawing FIG. 5
Annotated Drawing FIG. 5
Exhibit A